REMARKS

Claims 66, 68, 76-85, 117-127, and 129-130 are currently pending. Claims 66 and 117 have been amended to more precisely define the recombinant erythropoietin administered to the subject. The amendment to claims 66 and 117 is supported by the specification and does not add new matter.[1]

I. 35 U.S.C.112, First Paragraph Written Description Rejections

Reconsideration is requested of the rejection of claims 66 and 117 under 35 U.S.C. §112, first paragraph. These claims were rejected on the basis that they do not satisfy the written description requirement.

According to the Office claim 66 and 117 do not satisfy the written description requirement because the phrase "the recombinant erythropoietin being other than Epoetin Alfa or Beta" is not supported by the specification as originally filed. Claims 66 and 117 have been amended so as to remove the phrase "being other than Epoetin Alfa or Beta." The basis for this rejection, accordingly, has been removed.

Claim 66 has also been rejected on the asserted basis that the phrase "wherein prior treatment of the subject with a therapeutic amount of Epoetin Alfa or Beta did not provide a therapeutic benefit within a treatment period" is not supported by the specification. Claim 66 has been amended so that the subject is one that is "non responsive when treated with Epoetin Alfa or Beta." The specification clearly describes one aspect of the invention as a method for treating an anemic condition in a subject that **is non responsive** to a therapeutic amount of Epoetin Alfa or Beta by

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[1]Claims 66 and 117 have been amended by replacing "other than Epoetin Alfa or Beta" with "consisting of Epoetin Omega." Support for this amendment can be found in the specification on page 6, at lines 26-29.

administering to the subject a therapeutic amount of Epoetin Omega.[2] Moreover, Example 6 details results of a cross-over trial comparing treatment of renal patients suffering from anemia with Epoetin Alfa and Epoetin Omega.[3] As illustrated in figure 18 (depicting the results of Example 6), subjects unable to obtain the target hemoglobin level when administered Epoetin Alfa were able to obtain the target hemoglobin level when administered Epoetin Omega. In view of the disclosure, amended claim 66 is supported by the specification.

In addition, claim 117 has been rejected on the asserted basis that the phrase "wherein prior treatment of the subject with a therapeutic amount of Epoetin Alfa or Beta produced an adverse effect in the subject" is not supported by the specification. Claim 117 has been amended so that the subject is one that is "adversely effected when treated with Epoetin Alfa or Beta." The specification clearly describes one aspect of the invention as a method for treating an anemic condition in a subject that **is adversely effected** when treated with a therapeutic amount of Epoetin Alfa or Beta by administering to the subject a therapeutic amount of Epoetin Omega.[4] Additionally, the specification provides a detailed explanation regarding exactly what constitutes "adversely effected" as:

> ...an unwanted biological response, physiological condition, biological measurement, or an increase in risk thereof, that may occur following the administration of a pharmaceutical agent, particularly rHu EPO to a subject.[5]

Moreover, figure 4 illustrates clinical data showing the occurrence of several adverse side effects in subjects treated with Epoetin Alfa in comparison to subjects treated with Epoetin Omega. Example 5 of the specification additionally describes a

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[2]See page 6 of the specification at lines 26-29.

[3]See pages 55 to 57 of the specification.

[4]See page 6 of the specification at lines 26-29.

[5]See page 13 of the specification at lines 13-15.

subject initially administered Epoetin Beta and Alfa to treat chronic anemia where the subject suffered from adverse reactions such as swelling and itching of the lower legs. But when the same subject was treated with Epoetin Omega, the subject did not experience adverse reactions. In view of the disclosure, amended claim 117 is supported by the specification.

Claims 66 and 117, as detailed above, satisfy the written description requirement. Accordingly, applicant respectfully requests withdrawal of this rejection.

The specification, in accordance with the Office's suggestion, has also been amended on page 15, at line 4, so as to remove the phrases "For example, under the conditions of an exhypoxic polycythemic mice assay (see, Nature (1961)" and "40,000 to about 65,000 U/mg." With this amendment, the basis for the rejection to Amendment B has been removed. Applicant, therefore, respectfully requests withdrawal of this rejection.

II. 35 U.S.C.112, First Paragraph Enablement Rejections

Reconsideration is requested of the rejection of claims 66, 68, 76-85, 117-127, and 129-130. These claims were rejected on the asserted basis that they are not sufficiently enabled.

A. Claim 66 is sufficiently enabled by the specification

The Office asserts that claim 66 is not sufficiently enabled because the specification does not disclose that "prior treatment of the subject with a therapeutic amount of Epoetin Alfa or Beta did not provide a therapeutic benefit within a treatment period." Amended claim 66 is directed toward a subset of subjects that are "non responsive when treated with a therapeutically effective amount of Epoetin Alfa or Beta." To satisfy the enablement requirement, a skilled artisan must be able to make or use the **claimed** invention from the disclosures in the application coupled with

information known in the art without undue experimentation .[6] In this case, the specification specifically dictates that a number of subjects are "non-responsive to treatment with Epoetin Alfa or Beta, such that a response is absent"[7] and that one aspect of the invention encompasses treating an anemic condition in subjects that are non-responsive to Epoetin Alfa or Beta by administering to the subjects Epoetin Omega.[8] The specification also details results of a cross-over trial comparing treatment of renal patients suffering from anemia with Epoetin Alfa and Epoetin Omega.[9] As illustrated in figure 18 (depicting the results of Example 6), subjects unable to obtain the target hemoglobin level when administered Epoetin Alfa were able to obtain the target hemoglobin level when administered Epoetin Omega. In view of this disclosure, the phrase "non responsive when treated with a therapeutically effective amount of Epoetin Alfa or Beta," as employed in claim 66, is sufficiently enabled.

Moreover, as a matter of Patent Office practice, a specification that contains a teaching of the manner and process of making and using the invention is presumed to be enabled unless there is reason to doubt the objective truth of the statements contained in the specification. Furthermore, it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement made in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.[10] In this case, the Office action is devoid of any evidence or reasoning that explains why the Office doubts the truth or accuracy of the disclosure supporting treatment of subjects with Epoetin Omega that are "non-responsive to

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[6]U.S. v. Teletronics, Inc., 8 USPQ2d 1217 (Fed. Cir. 1988).

[7]See the specification on page 3, at lines 11-12.

[8]See page 6 of the specification at lines 26-29.

[9]See pages 55 to 57 of the specification.

[10]In re Marzocchi, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971).

treatment with Epoetin Alfa or Beta." Absent this reasoning, the Office has not supported its assertion that claim 66 in not sufficiently enabled in view of the use of the phrase "non-responsive to treatment with Epoetin Alfa or Beta."

According to the Office, claim 66 is not sufficiently enabled because the specification fails to teach a method using "any recombinant erythropoietin other than Epoetin Alfa or Beta." Claim 66, as amended, is directed toward the use of a recombinant erythropoietin "consisting of Epoetin Omega." As acknowledged by the Office, use of Epoetin Omega is enabled by the specification.[11] The basis for this rejection, therefore, has been removed.

The Office also asserts that claim 66 is also not sufficiently enabled because while the specification is enabling for a method of "treating," it is not enabling for a method of "preventing."[12] Claim 66 has been amended by deletion of "preventing." The basis for this rejection, therefore, has also been removed.

In view of the foregoing, applicant respectfully requests a withdrawal of the enablement rejection of claim 66. Moreover, claims 68 and 76-85, which depend from claim 66, are enabled for the reasons detailed with respect to claim 66.

B. Claim 117 is sufficiently enabled by the specification

Claim 117, as amended, is directed toward a method for treating an anemic condition in a subject. The method comprises administering to the subject a therapeutic amount of a recombinant erythropoietin produced in baby hamster kidney cells consisting of Epoetin Omega, where the subject is adversely effected when treated with a therapeutic amount Epoetin Alfa or Beta.

According to the Office, the specification **is enabling** for:

> ...a method for treating an anemic condition in a subject, the method comprising administering to the subject a therapeutic amount of a recombinant erythropoietin produced in baby hamster kidney cells,

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[11]See Paper 17 at page 7.

[12]See Paper 17 at page 7.

wherein the recombinant erythropoietin is Epoetin Omega, wherein the Epoetin Omega is selected to provide a therapeutic benefit within a treatment period and wherein said subject is adversely effected by treatment with a therapeutic amount of Epoetin Alfa or Beta.[13]

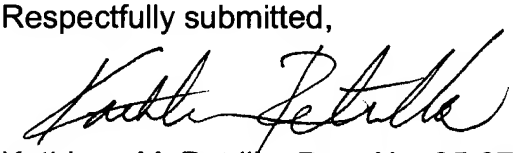
Amended claim 117 encompasses the subject matter detailed above that, according to the Office, is enabled by the specification. Moreover, claims 118-127 and 129-130, which depend from claim 117, are enabled for the reasons detailed with respect to claim 117. Applicant, therefore, requests a withdrawal of the rejection of claims 117-127 and 129-130 as non enabled.

III. Conclusion

In light of the foregoing, Applicant requests withdrawal of the final rejection, entry of the claim amendments, withdrawal of the claim rejections, and allowance of the claims. The Examiner is invited to contact the undersigned attorney should any issues remain unresolved.

Enclosed is a check for $1,280.00 for a three month extension of time and notice of appeal fee. If the Commissioner determines any additional fee is due, he is hereby authorized to charge said government fees to Deposit Account No. 19-1345.

Respectfully submitted,



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[13]See Paper 17 at page 5.